UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

JOHN HOLT
SR50 E. PO Box 92
Pelham, TN 37366

Plaintiff,

v.

SMITHKLINE BEECHAM CORPORATION
d/b/a GLAXOSMITHKLINE
One Franklin Plaza
Philadelphia, PA 19101-1225

Defendants

Case No._____

COMPLAINT AND DEMAND FOR JURY TRIAL

Plaintiff, by attorneys, THE BRANCH LAW FIRM, as and for the Verified Complaint herein allege upon information and belief the following:

STATEMENT OF THE CASE

1. This is an action to recover damages for personal injuries sustained by the Plaintiff, John Holt, (hereinafter referred to as "Plaintiff"), as the direct and proximate result of the wrongful conduct of the Defendants, SMITHKLINE BEECHAM CORPORATION, GLAXOSMITHKLINE and SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE, (hereinafter referred to as "Defendants" or "GSK"), in connection with the designing, developing, manufacturing, distributing, labeling, advertising, marketing, promoting, and selling of the widely-used diabetes

prescription drug marketed as Avandia, Avandamet, and Avandaryl (rosiglitazone maleate).

JURISDICTION AND VENUE

2. Jurisdiction exists as against the Defendants, SMITHKLINE BEECHAM CORPORATION, d/b/a GLAXOSMITHKLINE pursuant to:

a. 28 U.S.C. Section 1332, in that the Plaintiff, John Holt, is a citizen and resident of the State of Tennessee, the Defendant, SMITHKLINE BEECHAM CORPORATION, d/b/a GLAXOSMITHKLINE is a Pennsylvania corporation with its principal place of business and address at 1 Franklin Plaza, Philadelphia, Pennsylvania, and regularly conducts business in the State of Pennsylvania, and the amount in controversy exceeds the sum of $75,000.00 exclusive of interests and costs.

b. 28 U.S.C. Section 1391, in that jurisdiction is founded only on diversity of citizenship, and the Judicial District of the Eastern District of Pennsylvania is a Judicial District in which a substantial part of the events or omissions giving rise to the claim occurred.

PARTY PLAINTIFF

3. The Plaintiff, John Holt, is a natural person and a resident of the State of Tennessee.

PARTY DEFENDANTS

4. The Defendant, SmithKline Beecham Corporation d/b/a Glaxosmithkline, is a Pennsylvania corporation which has its principal place of business at One Franklin Plaza, 200 N. 16th Street, Philadelphia, Pennsylvania 19102.

5. At all times material hereto, the Defendant, SmithKline Beecham Corporation d/b/a GlaxoSmithKline was engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling Avandia.

6. Upon information and belief, the Defendant, SmithKline Beecham Corporation d/b/a Glaxosmithkline, was formed as a result of the merger of pharmaceutical corporations Glaxo Wellcome, Inc., and SmithKline Beecham, Inc.

7. At all times hereinafter mentioned, upon information and belief, GSK is a successor in interest to the defendant SmithKline Beecham Corporation.

8. On or about December 2000, defendant GSK assumed the assets and liabilities of defendant SmithKline Beecham Corporation.

BACKGROUND
STATEMENT OF THE CASE

9. Type 2 diabetes is the most common form of diabetes, afflicting 18 million Americans and 200 million people worldwide. This form of diabetes occurs when the body does not make enough insulin (a hormone needed to convert sugar and other food into energy) or cannot effectively use what it manages to produce.

10. Avandia, created and marketed by GSK, is designed to treat persons with Type 2 diabetes by helping sensitize cells to insulin, thereby greatly assisting in blood-sugar control. It also is combined with metformin and sold as Advandamet. Only one other drug like it, pioglitazone, sold as Actos and Actoplus, made by Takeda Pharmaceuticals, is sold in the United States. In 2006, Avandia represented 37% of the U.S. market for oral diabetes treatments. Thus, the U.S. market for such drugs is huge, and Avandia faces only one competitor for that market.

11. Avandia had a total U.S. sales of $2.2 billion in 2006, slightly less than the $2.6 billion in total U.S. sales for Actos, according to IMS Health, a healthcare information company. Approximately 13 million Avandia prescriptions were filled in the U.S. last year, with a one-month supply of Avandia selling for between $90 and $170. Avandia is critical to GSK, being the company's second largest selling drug after Advair (an asthma medication).

12. GSK's product Avandia can cause heart injury, excessive fluid retention, fluid-overload disease, liver damage, liver failure and severe injury to the heart leading to cardiac arrest and death. In 2005, GSK performed an overview analysis of multiple Avandia trials, referred to as a "meta-analysis", and shared the preliminary results with the Food and Drug Administration ("FDA") in September 2005. Almost one year later, in August 2006, a more complete version of the meta-analysis was provided to the FDA. The results of GSK's analysis showed that patients taking Avandia had a 31% higher risk of adverse cardiovascular events such as heart attack due to obstruction of blood flow.

13. GSK's Avandia can cause heart injury, excessive fluid retention, fluid-overload disease, liver damage, liver failure, and severe injury to the heart leading to cardiac arrest and death. Not only was GSK aware of the dangers posed by Avandia, but data from these studies continued to be made available to GSK. On May 21, 2007, Dr. Steven E. Nissen, a prominent cardiologist associated with the Cleveland Clinic, published a study in the New England Journal of Medicine of his analysis of 42 studies comprising of approximately 28,000 people who took Avandia. These were on-line databases of GSK studies that were available on the Internet. Dr. Nissen's meta-analysis revealed a 43% higher risk of heart attack for those taking Avandia compared to people

taking other diabetes drugs or no diabetes medication, and people taking Avandia suffered such adverse events at a rate of 1.99%, as opposed to 1.51% for other patients. Further, Dr. Nissen's analysis showed a 64% elevated risk of death from cardiovascular disease.

14. Despite GSK's longstanding knowledge of these dangers, Avandia's label only warns about possible heart failure and other heart problems when taken with insulin. GSK failed to adequately warn and disclose to consumers that Avandia significantly increased the risk of adverse cardiovascular events. Furthermore, the proper and effective use of Avandia by Plaintiff was impaired due to GSK's failure to adequately warn of Avandia's defects and GSK's failure to properly and adequately set forth such warnings in Avandia's drug labeling.

15. GSK knew of these dangerous defects in Avandia from the many trials which it performed and to which it had access and from its own analysis of these studies, but took no action to adequately warn or remedy the defects, but instead concealed, suppressed and failed to disclose these dangers. Even in the face of Dr. Nissen's study, GSK continues to fail to warn of these dangers through revised drug labeling.

16. Not only has GSK failed to disclose in its labeling or advertising that Avandia is actually dangerous for diabetics, GSK has represented and has continued to represent that they manufacture and/or sell safe and dependable pharmaceuticals with safety as their first concern:

> Like all innovative pharmaceutical companies, we carry out a series of clinical trials to test each investigational drug for the potential to become a new medicine.
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> ***
>
> Phase I trials typically involve health volunteers. *These trials study the safety of the drug and its interaction with the body*, for example, its concentration and

> duration in the blood following various doses, and begin to answer such questions as whether the drug inhibits or amplifies the effects of other medicines that might be taken at the same time.
>
> Phase II studies enroll patients with the illness an investigational drug is designed to treat. These trials evaluate whether the drug shows favorable effects in treating an illness and seek to determine the proper dose. They provide an opportunity to explore the therapeutic potential of the drug in what may be quite different illnesses. *The evaluation of safety continues*.
>
> If Phase II results have been encouraging, Phase III trials, the largest part of a clinical-development program, go forward. *Phase III trials are designed to provide the substantial evidence of efficacy and safety required*, in addition to data from earlier-phase trials, before regulatory agencies will approve the investigational drug as a medicine and allow it t o be marketed.

http://www.gsk.com/research/clinical/index/html (emphasis supplied).

17. GSK has also strongly touted their commitment to improving the quality of life: "We have a challenging and inspiring mission: to improve the qualify of human life by enabling people to do more, feel better and live longer." http://www.gsk.com/about/index.htm.

18. On May 21, 2007, the FDA issued a Safety Alert on Avandia showing that there is a potentially significant risk of heart attack and heart-related deaths in patients taking Avandia.

19. Based on these representations, upon which both Plaintiff and Plaintiff's prescribing physician relied, including the omission from the Avandia labeling of the danger of increased risk of adverse cardiovascular events as a result of ingesting Avandia, Plaintiff purchased and ingested Avandia believing that the drug would be safe and effective.

20. In fact, however, Avandia poses significant safety risks due to defects in its chemical design and inadequate labeling.

21. To date, GSK has failed to adequately warn or inform consumers, such as Plaintiff or Plaintiff's prescribing physician, of the known defects in Avandia that can lead to increased risks of cardiovascular events, including but not limited to heart injury, excessive fluid retention, fluid-overload disease, liver damage, liver failure, and severe injury to the heart leading to cardiac arrest, and death.

22. As a result of GSK's omissions and/or misrepresentations, Plaintiff ingested Avandia, suffered heart blockage on or around August 1, 2001, and sustained physical and financial damages including pain and suffering.

COUNT I
NEGLIGENCE

23. Plaintiff repeats and reiterates the allegations previously set forth herein.

24. That at all times hereinafter mentioned, Defendants were under a duty to exercise reasonable care in the design manufacture, testing processing, marketing advertising, labeling, packaging distribution, and sale of Avandia, and Defendants knew or should have known that Avandia was not safe and that the user could sustain injuries and harm from the drug.

25. That Defendants negligently, recklessly, grossly negligently, wantonly and willfully displayed a morally culpable and conscious disregard of the rights of others in that they failed to exercise reasonable care and failed to fulfill the above-stated duty by the manner that Defendants, directly and indirectly, advertised, marketed and promoted Avandia for the treatment of diabetes, even though Avandia, in fact, was not reasonably safe for such use, and furthermore, Defendants failed to adequately warn of the increased risk of serious cardiovascular events which Defendants knew or should have known about.

26. That Defendants negligently, recklessly, grossly negligently, wantonly and willfully displayed a morally culpable and conscious disregard of the rights of others by manufacturing, distributing, selling, advertising, marketing and promoting Avandia even though such drug was not safe or effective for any purpose because it caused serious cardiovascular events and by failing to adequately warn the trusting public and prescribing health care providers of the true, complete, and accurate risk and the lack of efficacy of Avandia.

27. The aforesaid incident and the injuries sustained by Plaintiff were caused by or were contributed to by the negligence, recklessness, gross negligence, wantonness, willfulness, and conscious and callous disregard of the safety of the public, including Plaintiff, on the part of Defendants in the design, manufacture, distribution, advertising, marketing and promoting of Avandia as being safe and effective in the treatment of diabetes, and by inducing the public, including Plaintiff and Plaintiff's prescribing physician, to believe that Avandia was effective in the treatment of the causes and symptoms of diabetes.

28. Defendants failed to exercise reasonable care in the design, manufacture, testing, processing, marketing, advertising, labeling, packaging, rebranding, distribution and/or sale of Avandia in one or more of the following respects:

a. Designing, marketing, processing, advertising, packaging, distributing and/or selling a product that defendants knew, or should have known, carried the risk of serious; life-threatening side effects;

b. Failure to adequately test the product prior to placing the drug Avandia on the market;

c. Failure to use care in designing, developing and manufacturing their product so as to avoid posing unnecessary health risks to users of such product;

d. Failure to conduct adequate pre-clinical testing and post-marketing surveillance to determine the safety of Avandia;

e. Failure to advise consumers, such as plaintiff, that consumption of Avandia could result in severe and disabling side effects, including but not limited to heart injury, excessive fluid retention, fluid-overload disease, liver damage, liver failure and severe injury to the heart leading to cardiac arrest and death.

f. Failure to advise the medical and scientific communities of the potential for severe and disabling side effects, including but not limited to heart injury, excessive fluid retention, fluid-overload disease, liver damage, liver failure, and severe injury to the heart leading to cardiac arrest, and death.

g. Failure to provide timely and/or adequate warnings about the potential health risks associated with the use of Avandia; and

h. Any and all other acts of negligence with respect to Avandia which may be shown at trial.

29. That at all times hereinafter mentioned, upon information and belief, the above-described culpable conduct by Defendants was a proximate cause of injuries sustained by Plaintiff.

30. That as a result of the aforesaid occurrence, the injuries sustained by Plaintiff resulting therefrom, Plaintiff suffered extensive monetary and pecuniary losses and other compensatory damages were also incurred and paid out including necessary medical, hospital, and concomitant expenses. In addition, Plaintiff was deprived of a chance for safe and effective and/or successful treatment.

31. By reason of the foregoing, Plaintiff sustained damages in a sum which exceeds the jurisdictional limits of all lower courts which would have jurisdiction of this matter, and in addition, Plaintiff seeks punitive and exemplary damages against Defendants in an amount to be determined upon the trial of this matter.

32. WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT II
NEGLIGENT FAILURE TO ADEQUATELY WARN

33. Plaintiff repeats and reiterates the allegations previously set forth herein.

34. At all relevant times, defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and otherwise released into the stream of commerce the pharmaceutical, Avandia, and in the course of same, directly advertised or marketed the product of FDA, consumers or persons responsible for consumers, and therefore had a duty to warn of the risks associated with the use of Avandia.

35. At all relevant times, Avandia was under the exclusive control of the Defendants as aforesaid, and was unaccompanied by appropriate warnings regarding all possible adverse side effects and complications associated with the use of Avandia, dangerous drug-drug interactions and food-drug interactions, and the comparative severity, duration and the extent of the risk of injury with such use.

36. At all relevant times, defendants failed to timely and reasonably warn of material facts regarding the safety and efficacy of Avandia so that no reasonable medical care provider would have prescribed, or no consumer would have used, Avandia had those facts been made known to such providers and consumers.

37. At all relevant times, defendants failed to perform or otherwise facilitate adequate testing in that such testing would have shown that Avandia posed serious and potentially life-threatening side effects and complications with respect to which full and

proper warning accurately and fully reflecting the symptoms, scope and severity should have been made to medical care providers, the FDA and the public, including Plaintiff.

38. At all relevant times, Avandia, which was researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and otherwise released into the stream of commerce by Defendants, was defective due to inadequate post-marketing warning and/or instruction because, after Defendants knew or should have known of the risk of serious and potentially life-threatening side effects and complications from the use of Avandia, Defendants failed to provide adequate warnings to medical care providers, the FDA and the consuming public, including Plaintiff, and continued to promote Avandia aggressively.

39. As a direct and proximate result of Defendants' carelessness and negligence, the Plaintiff suffered severe and permanent physical injuries. The Plaintiff has endured substantial pain and suffering and has undergone extensive medical and surgical procedures. Plaintiff has incurred significant expenses for medical care and treatment, and will continue to incur such expenses in the future. The Plaintiff has lost past earnings and has suffered a loss of earning capacity. The Plaintiff has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally and economically injured. The Plaintiff's injuries and damages are permanent and will continue into the future. The Plaintiff seeks actual and punitive damages from the Defendants as alleged herein.

40. WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT III
NEGLIGENCE *PER SE*

41. Plaintiff repeats and reiterates the allegations previously set forth herein.

42. At all times mentioned herein, Defendants had an obligation not to violate the law, in the manufacture, design, formulation, compounding, testing, production, processing, assembling, inspection, research, distribution, marketing, labeling, packaging preparation for use, sale and warning of the risks and dangers of the aforementioned product.

43. At all times herein mentioned, Defendants violated the Federal Food, Drug and Cosmetic Act, 21 U.S.C. Section 301 *et seq.*, related amendments and codes and federal regulations provided thereunder, and other applicable laws, statutes and regulations.

44. Plaintiff, as a purchaser and consumer of the product, is within the class of persons the statutes and regulations described above are designed to protect, and the injuries alleged herein are the type of harm these statutes are designed to prevent.

45. Defendants' acts constitute an adulteration and/or misunderstanding as defined by the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 331, and constitutes a breach of duty subjecting Defendants to civil liability for all damages arising therefrom, under theories of negligence *per se.*

46. Defendants failed to meet the standard of care set by the applicable statutes and regulations, which were intended for the benefit of individuals such as Plaintiff, making Defendants negligent *per se*: (a) the labeling lacked adequate information on the use of the drug Avandia; (b) the labeling failed to provide adequate warnings of severe and disabling medical conditions as soon as there was reasonable

evidence of their association with the drug; (c) there was inadequate information for patients for the safe and effective use of Defendants' drug; (d) there was inadequate information regarding special care to be exercised by the doctor for safe and effective use of Defendants' drug; and (e) the labeling was misleading and promotional.

47. As a direct and proximate result of Defendants' carelessness and negligence, the Plaintiff suffered severe and permanent physical injuries. The Plaintiff has endured substantial pain and suffering and has undergone extensive medical and surgical procedures. Plaintiff has incurred significant expenses for medical care and treatment, and will continue to incur such expenses in the future. The Plaintiff has lost past earnings and has suffered a loss of earning capacity. The Plaintiff has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally and economically injured. The Plaintiff's injuries and damages are permanent and will continue into the future. The Plaintiff seeks actual and punitive damages from the Defendants as alleged herein.

48. WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT IV
NEGLIGENT MISREPRESENTATION

49. Plaintiff repeats and reiterates the allegations previously set forth herein.

50. Defendants, in addition to knowing misrepresentations, made misrepresentations without any reasonable grounds for believing its statements to be true to Plaintiff, other patients, and the medical community.

51. Defendants, through their misrepresentations, intended to induce justifiable reliance by Plaintiff, other patients, and the medical community.

52. Defendants, through their marketing campaign and communications with treating physicians, were in a relationship so close to that of Plaintiff and other patients that it approaches and resembles privity.

53. Defendants owed a duty to the medical community, Plaintiff, and other consumers, to conduct appropriate and adequate studies and tests for all products, including Avandia, and to provide appropriate and adequate information and warnings.

54. Defendants failed to conduct appropriate or adequate studies for Avandia.

55. Defendants failed to exercise reasonable care by failing to conduct studies and tests of Avandia.

56. As a direct and proximate result of Defendants' carelessness and negligence, the Plaintiff suffered severe and permanent physical injuries. The Plaintiff has endured substantial pain and suffering and has undergone extensive medical and surgical procedures. Plaintiff has incurred significant expenses for medical care and treatment, and will continue to incur such expenses in the future. The Plaintiff has lost past earnings and has suffered a loss of earning capacity. The Plaintiff has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally and economically injured. The Plaintiff's injuries and damages are permanent and will continue into the future. The Plaintiff seeks actual and punitive damages from the Defendants as alleged herein.

57. WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT V
BREACH OF EXPRESS WARRANTY

58. Plaintiff repeats and reiterates the allegations previously set forth herein.

59. Defendants expressly represented to Plaintiff and other consumers and the medical community that Avandia was safe and fit for its intended purposes, that is was of merchantable quality, that it did not produce any dangerous side effects, and that it was adequately tested.

60. Avandia does not conform to Defendants' express representations because it is not safe, has numerous and serious side effects, and causes severe and permanent injuries.

61. At all relevant times Avandia did not perform as safely as an ordinary consumer would expect, when used as intended or in a reasonably foreseeable manner.

62. Plaintiff, other consumers, and the medical community relied upon Defendants' express warranties.

63. As a direct and proximate result of the Defendants' breach of express warranty, the Plaintiff suffered severe and permanent physical injuries. The Plaintiff has endured substantial pain and suffering and has undergone extensive medical and surgical procedures. Plaintiff has incurred significant expenses for medical care and treatment, and will continue to incur such expenses in the future. Plaintiff has lost past earnings and has suffered a loss of earning capacity. The Plaintiff has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally, and economically

injured. The Plaintiff's injuries and damages are permanent and will continue into the future. The Plaintiff seeks actual and punitive damages from the Defendants as alleged herein.

64. Defendants' conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish them and deter it from similar conduct in the future.

65. WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT VI
BREACH OF IMPLIED WARRANTY

66. Plaintiff repeats and reiterates the allegations previously set forth herein.

67. The Defendants designed, manufactured, marketed, distributed, supplied and sold the subject product for the treatment of diabetes.

68. At the time that the Defendants manufactured, marketed, distributed, supplied, and/or sold Avandia, they knew of the use for which the subject product was intended and impliedly warranted it to be of merchantable quality and safe and fit for such use.

69. The Plaintiff, individually and through a prescribing physician, reasonably relied upon the skill, superior knowledge and judgment of the Defendants.

70. The Plaintiff was prescribed, purchased, and used the subject product for its intended purpose.

71. Due to Defendants' wrongful conduct as alleged herein, the Plaintiff could not have known about the nature of the risks and side effects associated with the subject product until after use.

72. Contrary to the implied warranty for the subject product, Avandia was not of merchantable quality, and was not safe or fit for its intended uses and purposes as alleged herein.

73. As a direct and proximate result of the Defendants' breach of implied warranty, the Plaintiff suffered severe and permanent physical injuries. The Plaintiff has endured substantial pain and suffering and has undergone extensive medical procedures. Plaintiff has incurred significant expenses for medical care and treatment, and will continue to incur such expenses in the future. The Plaintiff has lost past earnings and has suffered a loss of earning capacity. The Plaintiff has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally and economically injured. The Plaintiff's injuries and damages are permanent and will continue into the future. The Plaintiff seeks actual and punitive damages from the Defendants as alleged herein.

74. WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT VII
STRICT PRODUCTS LIABILITY – DEFECTIVE DESIGN

75. Plaintiff repeats and reiterates the allegations previously set forth herein.

76. At all times material to this action, the Defendants were responsible for designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling Avandia.

77. The subject product is defective and unreasonably dangerous to consumers.

78. Avandia is defective in its design or formulation in that it is not reasonably fit, suitable, or safe for its intended purpose and/or its foreseeable risks exceed the benefits associated with its design and formulation.

79. At all times material to this action, Avandia was expected to reach, and did reach, consumers in this jurisdiction and through the United States, including the Plaintiff herein, without substantial change in the condition in which it was sold.

80. At all times material to this action, Avandia was designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled, and/or sold by Defendants in a defective and unreasonably dangerous condition at the time it was placed in the stream of commerce in ways which include, but are not limited to, one or more of the following particulars:

a. When placed in the stream of commerce, Avandia contained unreasonably dangerous design defects and was not reasonably safe as intended to be used, subjecting the Plaintiff to risks that exceeded the benefits of the subject product, including but not limited to the risks of developing heart injury, excessive fluid retention, fluid-overload disease, liver damage, liver failure, and severe injury to the heart leading to cardiac arrest and death and other serious injuries and side effects in an unacceptably high number of its users;

b. When placed in the stream of commerce, Avandia was defective in design and formulation, making the use of Avandia more dangerous

than an ordinary consumer would expect, and more dangerous than other risks associated with the other medications and similar drugs on the market for the treatment of diabetes;

c. The subject product's design defects existed before it left the control of the Defendants;

d. Avandia was insufficiently tested;

e. Avandia caused harmful side effects that outweighed any potential utility; and

f. Avandia was not accompanied by adequate instructions and/or warnings to fully apprise consumers, including the Plaintiff herein, of the full nature and extent of the risks and side effects associated with its use, thereby rendering Defendants liable to Plaintiff, individually and collectively.

81. In addition, at the time the subject product left the control of the Defendants, there were practical and feasible alternative designs that would have prevented and/or significantly reduced the risk of Plaintiff's injuries without impairing the reasonably anticipated or intended function of the product. These safer alternative designs were economically and technologically feasible, and would have prevented or significantly reduced the risk of Plaintiff's injuries without substantially impairing the product's utility.

82. As a direct and proximate result of the subject product's defective design, the Plaintiff suffered severe and permanent physical injuries. The Plaintiff has endured substantial pain and suffering and has undergone extensive medical and surgical

procedures. Plaintiff has incurred significant expenses for medical care and treatment, and will continue to incur such expenses in the future. The Plaintiff has lost past earnings and has suffered a loss of earning capacity. The Plaintiff has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally and economically injured. The Plaintiff's injuries and damages are permanent and will continue into the future. The Plaintiff seeks actual and punitive damages from the Defendants as alleged herein.

83. WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT VIII
STRICT PRODUCTS LIABILITY – MANUFACTURING AND DESIGN DEFECT

84. Plaintiff repeats and reiterates the allegations previously set forth herein.

85. At all times material to this action, Defendants were engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling Avandia.

86. At all times material to this action, Avandia was expected to reach, and did reach, consumers in this jurisdiction and throughout the United States, including the Plaintiff herein without substantial change in the condition in which it was sold.

87. At all times material to this action, Avandia was designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled, and/or sold by Defendants in a defective and unreasonably dangerous condition at the time it was placed

in the stream of commerce in ways which include, but are not limited to, one or more of the following particulars:

a. When placed in the stream of commerce, Avandia contained manufacturing defects which rendered the product unreasonably dangerous;

b. The subject product's manufacturing defects occurred while the product was in the possession and control of the Defendants;

c. The subject product was not made in accordance with the Defendants' specifications and performance standards;

d. The subject product's manufacturing defects existed before it left the control of the Defendants;

88. As a direct and proximate result of the subject product's manufacturing defects, the Plaintiff suffered severe and permanent physical injuries. The Plaintiff has endured substantial pain and suffering and has undergone extensive medical and surgical procedures. Plaintiff has incurred significant expenses for medical care and treatment, and will continue to incur such expenses in the future. The Plaintiff has lost past earnings and has suffered a loss of earning capacity. The Plaintiff has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally and economically injured. The Plaintiff's injuries and damages are permanent and will continue into the future. The Plaintiff seeks actual and punitive damages from the Defendants as alleged herein.

89. WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT IX
STRICT PRODUCTS LIABILITY – FAILURE TO ADEQUATELY WARN

90. Plaintiff repeats and reiterates the allegations previously set forth herein.

91. Avandia was defective and unreasonably dangerous when it left the possession of the Defendants in that it contained warnings insufficient to alert consumers, including the Plaintiff herein, of the dangerous risks and reactions associated with the subject product, including but not limited to its propensity to cause heart injury, excessive fluid retention, fluid-overload disease, liver damage, liver failure, and severe injury to the heart leading to cardiac arrest and death and other serious injuries and side effects over other forms of diabetes treatment.

92. The Plaintiff was prescribed and used the subject product for its intended purpose.

93. The Plaintiff could not have discovered any defect in the subject product through the exercise of reasonable care.

94. The Defendants, as manufacturers and/or distributors of the subject prescription product, are held to the level of knowledge of an expert in the field.

95. The warnings that were given by the Defendants were not accurate, clear and/or were ambiguous.

96. The warnings that were given by the Defendants failed to properly warn physicians of the increased risks of heart injury, excessive fluid retention, fluid-overload

disease, liver damage, liver failure, and severe injury to the heart leading to cardiac arrest and death and other serious injuries and side effects.

97. The warnings that were given by the Defendants failed to properly warn consumers of the increased risks of heart injury, excessive fluid retention, fluid-overload disease, liver damage, liver failure, and severe injury to the heart leading to cardiac arrest and death and other serious injuries and side effects.

98. The Plaintiff, individually and through a prescribing physician, reasonably relied upon the skill, superior knowledge and judgment of the Defendants.

99. The Defendants had a continuing duty to adequately warn the Plaintiff of the dangers associated with the subject product and of the poor efficacy of the product.

100. Had the Plaintiff and/or Plaintiff's prescribing physician received adequate warnings regarding the risks, and the lack of benefits, of the subject product, Plaintiff would not have used it.

101. As a proximate result of the subject product's manufacturing defects, the Plaintiff suffered severe and permanent physical injuries. The Plaintiff has endured substantial pain and suffering and has undergone extensive medical and surgical procedures. Plaintiff has incurred significant expenses for medical care and treatment, and will continue to incur such expenses in the future. The Plaintiff has lost past earnings and has suffered a loss of earning capacity. The Plaintiff has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally and economically injured. The Plaintiff's injuries and damages are permanent and will continue into the future. The Plaintiff seeks actual and punitive damages from the Defendants as alleged herein.

102. WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT X
FRAUDULENT MISREPRESENTATION

103. Plaintiff repeats and reiterates the allegations previously set forth herein.

104. Defendants widely advertised and promoted Avandia as a safe and effective medication both in direct-to-consumer marketing and in fraudulent promotion to the health care providers including Plaintiff's prescribing physician.

105. Defendants had a duty to disclose material information about serious side effects to consumers such as Plaintiff. Additionally by virtue of Defendants' partial disclosures about the medication, in which Defendants touted Avandia as safe and effective treatment, Defendants had a duty to disclose all facts about the risks of use associated with the medication, including the potential for the medication to cause heart injury, excessive fluid retention, fluid-overload disease, liver damage, liver failure, and severe injury to the heart leading to cardiac arrest, and death. Defendants intentionally failed to adequately disclose this information for the purpose of inducing consumers, such as Plaintiff, to purchase Defendants' dangerous product.

106. Had Plaintiff been aware of the hazards associated with Avandia, Plaintiff would not have consumed the product that lead proximately to Plaintiff's adverse health effects.

107. Defendants' advertisements regarding Avandia made material misrepresentations to the effect that Avandia was a safe and effective treatment, which misrepresentations Defendant knew to be false, for the purpose of fraudulently inducing

consumers, such as Plaintiff, to purchase such product. Plaintiff relied in part on these material misrepresentations in deciding to purchase and consume Avandia to his detriment.

108. The damages sustained by Plaintiff were a direct and foreseeable result of, and were proximately caused by Defendants' misrepresentations, concealment and omissions.

109. Defendants' conduct was willful, wanton, and reckless. Based on the intentionally dishonest nature of Defendants' conduct, which was directed at Plaintiff and the public generally, Defendants should also be held liable for punitive damages.

110. Any applicable statutes of limitation have been tolled by Defendants' knowing and active concealment and denial of the facts alleged herein. Plaintiff and other members of the public who were prescribed and who ingested Avandia for the treatment of diabetes have been kept in ignorance of vital information essential to the pursuit of these claims, without any fault or lack of diligence on their part, and could not reasonably have discovered the fraudulent nature of Defendants' conduct, and information and documents concerning the safety and efficacy of Avandia. Furthermore, due to the aforesaid allegations, Plaintiff may rely on the discovery rule in pursuit of this claim.

111. By reason of the foregoing, Plaintiff sustained damages in a sum which exceeds the jurisdictional limits of all lower courts which would have jurisdiction of this matter, and in addition thereto, Plaintiff seeks punitive and exemplary damages against Defendants in an amount to be determined upon the trial of this matter.

112. WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT XI
VIOLATIONS OF PENNSYLVANIA UNFAIR TRADE PRACTICES AND CONSUMER PROTECTION LAW

113. Plaintiff repeats and reiterates the allegations previously set forth herein.

114. At all relevant times there was in effect the Pennsylvania Unfair Trade Practices and Consumer Protection Law, 73 Pa. Stat. § 201-1 et seq. ("UTPCPL").

> Section 3 of the UTPCPL, 73 Pa. Stat. § 201-3, provides, in pertinent part: Unfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce as defined by sub clauses (I through (xxi) of clause (4) of section 2 of this act … are hereby declared unlawful.

115. Section 2 of the UTPCPL, 73 Pa. Stat. § 201-2, provides, in pertinent part:

> "UNFAIR METHODS OF COMPETITION" and UNFAIR OR DECEPTIVE ACTS OR PRACTICES" mean any one or more of the following:
>
> (v) Representing that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits or quantities that they do not have or that person has a sponsorship, approval, status, affiliation or connection that he does not have;
>
> (vii) Representing that goods or services are of a particular standard, qualify or grade or that goods are of a particular style or model, if they are of another;
>
> (xiv) Failing to comply with the terms of any written guarantee or warranty given to the buyer at, prior to or after a contract for the purchase of goods or services is made;
>
> (xxi) Engaging in any other fraudulent or deceptive conduct which creates a likelihood of confusion or of misunderstanding.

116. Defendants acted, used and employed deception, unfair and deceptive acts and practices, fraud, false promises, misrepresentations, concealment, suppression and

omission of material facts with intent that physicians and medical providers rely upon such concealment, suppression and omission, and for the purpose of influencing and inducing physicians and medical providers to prescribe Avandia, for the treatment of diabetes to patients/consumers such as Plaintiff, and causing such patients/consumers to purchase, acquire and use Avandia for the treatment of diabetes, as prescribed by their physicians and medical providers, in connection with the sale and advertisement of the drug Avandia, in violation of the UTPCPL.

117. By reason of Defendants' acts, uses and employment of deception, unfair and deceptive acts and practices, fraud, false promises, misrepresentations, concealment, suppression and omission of material facts, reasonable patients/consumers acting reasonably, such as Plaintiff, were caused to purchase and ingest Avandia, and thereby sustain serious personal injuries.

118. By reason of the foregoing, Plaintiff sustained damages in a sum which exceeds the jurisdictional limits of all lower courts which would have jurisdiction of this matter, and in addition thereto, Plaintiff seeks punitive and exemplary damages against Defendants in an amount to be determined upon the trial of this matter.

COUNT XII
UNJUST ENRICHMENT

119. Plaintiff repeats and reiterates the allegations previously set forth herein.

120. To the detriment of Plaintiffs the Defendants have been, and continue to be, unjustly enriched as a result of the unlawful and/or wrongful collection of, inter alia, payments for Avandia.

121. Plaintiffs were injured by the cumulative and indivisible nature of the Defendants' conduct. The cumulative effect of the Defendants' conduct directed at

physicians and consumers was to artificially create a demand for Avandia at an artificially inflated price. Each aspect of the Defendants' conduct combined to artificially create sales of Avandia.

122. The Defendants have unjustly benefited through the unlawful and/or wrongful collection of, inter alia, payments for Avandia and continue to so benefit to the detriment and at the expense of Plaintiffs.

123. Accordingly, Plaintiffs seek full disgorgement and restitution of the Defendants' enrichment, benefits, and ill-gotten gains acquired as a result of the unlawful and/or wrongful conduct alleged herein.

124. WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT XIII
PUNITIVE DAMAGES

125. Plaintiff repeats and reiterates the allegations previously set forth herein.

126. At all times material hereto, the Defendants knew or should have known that the subject product was inherently more dangerous with respect to the risks of heart injury, excessive fluid retention, fluid-overload disease, liver damage, liver failure, and severe injury to the heart leading to cardiac arrest, and death than alternative treatments for diabetes.

127. At all times material hereto, the Defendants attempted to misrepresent and did misrepresent facts concerning the safety of the subject product.

128. Defendants' misrepresentations included knowingly withholding material information from the medical community and the public, including the Plaintiff herein, concerning the safety of the subject product.

129. At all times material hereto, the Defendants knew and recklessly disregarded the fact that Avandia causes debilitating and potentially lethal side effects with greater frequency than safer alternative methods of treatment for diabetes.

130. Notwithstanding the foregoing, the Defendants continued to aggressively market the subject product to consumers, including the Plaintiff herein, without disclosing the aforesaid side effects when there were safer alternative methods of treatment for diabetes.

131. The Defendants knew of the subject product's defective and unreasonably dangerous nature, as set forth herein, but continued to design, develop, manufacture, market, distribute and sell it so as to maximize sales and profits at the expense of the health and safety of the public, including the Plaintiff herein, in conscious and/or negligent disregard of the foreseeable harm caused by Avandia.

132. Defendants intentionally concealed and/or recklessly failed to disclose to the public, including the Plaintiff herein, the potentially life threatening side effects of Avandia in order to ensure continued and increased sales.

133. The Defendants' intentional and/or reckless failure to disclose information deprived the Plaintiff of necessary information to enable Plaintiff to weight the true risks of using the subject product against its benefits.

134. As a direct and proximate result of the Defendants' conscious and deliberate disregard for the rights and safety of consumers such as the Plaintiff, the

Plaintiff suffered severe and permanent physical injuries. The Plaintiff has endured substantial pain and suffering and has undergone extensive medical and surgical procedures. Plaintiff has incurred significant expenses for medical care and treatment, and will continue to incur such expenses in the future. The Plaintiff has lost past earnings and has suffered a loss of earning capacity. The Plaintiff has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally and economically injured. The Plaintiff's injuries and damages are permanent and will continue into the future.

135. The aforesaid conduct of Defendants was committed with knowing, conscious, and deliberate disregard for the rights and safety of consumers, including the Plaintiff herein, thereby entitling the Plaintiff to punitive damages in an amount appropriate to punish the Defendants and deter them from similar conduct in the future.

136. WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

PRAYER FOR RELIEF

WHEREFORE, the Plaintiff prays for judgment against Defendants as follows:

(1) Judgment for plaintiff and against defendants;

(2) Damages in the form of compensatory damages in excess of the jurisdictional limits, trebled on all applicable counts;

(3) Physical pain and suffering of the Plaintiff

(4) Pre and post judgment interest at the lawful rate;

(5) Reasonably attorneys' fees and costs and expert fees;

(6) A trial by jury on all issues of the case;

(7) For any other relief as this court may deem equitable and just;

(8) Restitution of all purchase costs that Plaintiff paid for Avandia disgorgement of Defendants' profits, and such other relief as provided by law;

(9) Exemplary and punitive damages in an amount in excess of the jurisdictional limits, trebled on all applicable counts;

(10) All Bill of Costs elements; and

(11) Such other relief this Court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiff demands a jury trial on all claims so triable in this action.

Dated: November 9, 2009

Respectfully submitted,

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